

REMARKS

The Applicant has amended claims 23, 34, 37, 40, and 50-57 to clarify issues for appeal and to further prosecution. Support for the amendments is found generally in the application as filed, and at least at page 39, line 8 to page 40, line 6 and Fig. 1. No new matter is added. Entry of the amendments is respectfully requested.

Claim 34 is amended to correct an obvious typographical error, i.e., to replace “ruminitis” with “rumenitis.” Claim 37 is amended to correct obvious typographical errors, i.e., to delete an additional “at least” that was apparently introduced in the Response to the Office Action mailed June 29, 2007, and to replace “ruminitis” with “rumenitis.” Claim 40 is amended to correct an obvious typographical error, i.e., replacing “Elsdenii” with “elsdenii.”

The Applicant respectfully requests that the evidence provided in the accompanying DECLARATION OF JANE A. Z. LEEDLE, PH.D. UNDER 37 C.F.R. § 1.132 (the “Declaration”) be admitted and considered. The Declaration is timely submitted since it provides necessary evidence concerning the difference between the presently claimed invention and the prior art, a long-felt need, and the failure of others to produce the presently claimed invention. The declaration could not have been presented previously because the Office Action dated December 12, 2007 presented new ground(s) of rejection. The Declaration thus satisfies the requirements of 37 C.F.R. § 1.116(e).

Claim Objection

Claim 55 has been amended to correct the misspelling of “lasalocid.” In view of the amendment of claim 55, the Applicant respectfully requests that the objection be withdrawn.

Claim Rejections under 35 U.S.C. § 112 second paragraph

Claims 51-57 have been amended to make these claims dependent on claim 40. In view of these amendments, the Applicant respectfully requests that the rejections of claims 51-57 under 35 U.S.C. § 112 second paragraph be withdrawn.

Claim Rejections under 35 U.S.C. §103(a)

Claims 23, 24 and 26-57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Leedle et al., U.S. Patent No. 5,380,525. In view of the present amendments, the Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of claims 23, 24 and 26-57 is unwarranted and request that the rejection be withdrawn. The Examiner should reconsider any obviousness determination in view of the entire record, including the evidence provided in the accompanying Declaration. *See e.g., In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976), (“An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability.”); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 90 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990).

35 U.S.C. §103(a), quoted in the rejection, requires an evaluation of whether “the differences between the subject matter sought to be patented and the prior art are such that the ***subject matter as a whole*** would be obvious . . .” (*emphasis added*). The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459, 473 (1966). The Supreme Court has recently reaffirmed the *Graham* analysis. “[T]he scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1388 (U.S. 2007).

The findings of fact in the Office Action dated December 12, 2007 are an example of a piecemeal attempt to show the presence of individual elements of the present invention in the Leedle et al. reference instead of finding the differences between the prior art and the claimed invention as a whole. For example, the Office Action states:

In general organisms sharing more than 97% ribosomal RNA similarity **may** belong to a single species and **since** the biologically pure bacterial culture disclosed by Leedle et al. belongs to a *M. elsdenii* species **therefore, it must**

display at least 97% similarity to a 16S ribosomal RNA (rRNA) sequence with the claimed bacterial strain . . . (page 5, lines 2-5, emphasis added).

The Applicant submits that this finding of fact is based on substantive error. In fact, the Leedle et al. reference does not disclose that their strain 407A definitely belongs to a *M. elsdenii* species, but states “growth of 407A in lactate-containing media at pH 5.0 in the presence of monensin may place this bacterium in a taxonomic group other than *M. elsdenii*” (column 12, lines 60-63), further stating that “407A may be a new species or subspecies of the genus *Megasphaera*” (column 14, lines 48-49). See also Leedle et al., column 14, lines 62-67.

There is no evidence of record regarding the actual sequence of the 16S ribosomal RNA of any of the strains disclosed by the Leedle et al. reference. Given the speculative nature of the Office Action on this point (“In general,” and “may belong to a single species”) and since the Leedle et al. reference specifically leaves open the issue that the strain 407A may be a new species or subspecies of the genus *Megasphaera*, the cited reference cannot necessarily disclose or suggest all elements of the presently claimed invention as a whole.

With respect to the presently claimed invention, the Leedle et al. reference is silent on whether the strains disclosed therein are able to proliferate at pH 4.5. As noted in the accompanying Declaration, the ability to replicate at a measurable rate at pH 4.5 was missing from the characterized strains that were previously available (Declaration, paragraph 13). Since the cited reference does not disclose or suggest the presently claimed invention as a whole, the Applicant respectfully suggests that the rejection of claims 23, 24 and 26-57 under 35 U.S.C. §103(a) is unwarranted and should be withdrawn.

The accompanying Declaration provides evidence of a longstanding unmet need for the claimed invention and the failure of others to provide the claimed invention.

CONCLUSION

In light of the amendments and arguments presented herein, the Applicant respectfully submits that all pending claims are in condition for allowance and requests a timely Notice of Allowance to follow in this case. The Applicant requests that the Examiner telephone the

undersigned at (508) 860-1472 in the event that a telephone discussion would be helpful in advancing the prosecution of the present case.

A Request for Continued Examination and the required fee are submitted herewith. A two-month extension of time is hereby requested, and the required fee is submitted herewith. It is believed that no further fees are due with this filing. However, if any fees and/or credits are due, the undersigned authorizes any requisite fees or credits to be charged or credited to Account No. 50-1582.

Respectfully submitted,

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